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REMARKS

Applicant wishes to thank Examiner Smith for the courtesies extended by the Examiner in the telephonic interview on December 21, 2006 with Rebecca Ball, Applicant's undersigned attorney, Jill Powlick, Esq., and David Eyre, the inventor for the above-captioned application. Proposed amendments to claim 18 were discussed. An agreement was not reached with respect to allowance of the claims because the Examiner will update her search, but the Examiner indicated that the proposed amendments appear to overcome the rejections of record.

Claim 25 has been canceled without prejudice. Claim 18 has been amended to require that the processor is programmed "to determine whether the sample is indeterminate for the presence of the nucleic acid." Claim 18 has also been amended to delete the word "using" and the phrase "to use" and to clarify the data manipulations intended by the uses of algorithms and fluorescent values as requested by the Examiner. Support for the amendments made to claim 18 is found, for example, on page 11, lines 21-23, page 13, line 22 through page 14, line 31, and page 20, lines 4-31 of the specification. Minor amendments have been made to claims 20 and 21. Claim 26 has been added. New claim 26 contains subject matter of previous claim 18.

Rejection of Claims 18-23 and 25 under 35 U.S.C. § 112, ¶ 2

The Examiner has rejected claims 18-23 and 25 under 35 U.S.C. § 112, ¶ 2 as being indefinite. The Examiner indicates that the word "using" and the phrase "to use" are vague and indefinite. Claim 25 has been canceled without prejudice. As discussed in the December 21, 2006 telephonic interview, claim 18, and its dependent claims 19-23 have been amended to clarify the data manipulations intended by the uses of algorithms and fluorescent values as requested by the Examiner. Support for the amendments made to claim 18 is found,

for example, on page 11, lines 21-23, page 13, line 22 through page 14, line 31, and page 20, lines 4-31 of the specification. Each of the claim amendments is "expressly, implicitly, or inherently supported in the original disclosure" as required by MPEP §§ 2163.02 and 2163.05 and the case law that these MPEP provisions cite. See *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976), and *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998). Withdrawal of the rejection of claims 18-23 under 35 U.S.C. § 112, ¶ 2 is respectfully requested.

Rejection of Claims 18, 22, and 23 under 35 U.S.C. §§ 102(e) and 102(f)

The Examiner has rejected claims 18, 22, and 23 under 35 U.S.C. §§ 102(e) and 102(f) as being anticipated by U.S. Patent No. 6,387,621 by Wittwer et al. (hereinafter the '621 patent). Claim 18 has been amended to require that the processor is programmed "to determine whether the sample is indeterminate for the presence of the nucleic acid" rather than specifying that the processor is programmed to determine, in the alternative, whether the sample is "positive, negative, or indeterminate" for the presence of the nucleic acid. Applicant respectfully traverses the Examiner's rejection as to amended claims 18, 22, and 23. Amended claims 18, 22, and 23 are not anticipated by the '621 patent.

Anticipation exists only if all the elements of the claimed invention are present in a product or process disclosed, expressly or inherently, in a single prior art reference. *Hazeltine Corp. v. RCA Corp.*, 468 U.S. 1228 (1984). Claim 18 has been amended to specify that the processor is programmed "to determine whether the sample is *indeterminate* for the presence of the nucleic acid." As indicated by the Examiner during the telephonic interview, the '621 patent does not disclose determining whether the sample is *indeterminate* for the presence of the nucleic acid. In fact, the Examiner stated on page 8, line 18 of the September 5, 2006 office action that the '621 patent "discloses positive and negative determinations."

The amended claims 18, 22, and 23 require that the processor be programmed to “to determine whether the sample is indeterminate for the presence of the nucleic acid” and the ‘621 patent does not disclose this necessary element of claims 18, 22, and 23. Thus, the ‘621 patent cannot anticipate amended claims 18, 22, and 23 because the ‘621 patent does not describe a required element of amended claims 18, 22, and 23. Withdrawal of the rejection of claims 18, 22, and 23 under 35 U.S.C. §§ 102(e) and 102(f) is respectfully requested.

Rejection of Claims 19-21 and 25 under 35 U.S.C. § 103(a)

The Examiner has also rejected claims 19-21 and 25 under 35 U.S.C. § 103(a) as being obvious over the ‘621 patent in view of Schork et al. (U.S. Patent No. 6,291,182; hereinafter the ‘182 patent). Claim 25 has been canceled. Applicant respectfully traverses the Examiner’s rejection. The invention of amended claims 19-21 is not obvious over the ‘621 patent in view of the ‘182 patent.

Claim 18 has been amended to require that the processor is programmed “to determine whether the sample is indeterminate for the presence of the nucleic acid.” As indicated by the Examiner during the telephonic interview, the ‘621 patent does not disclose or suggest determining whether the sample is *indeterminate* for the presence of the nucleic acid. In rejecting claims 19-21 as being obvious over the ‘621 patent in view of the ‘182 patent, the Examiner has relied on the ‘182 patent for disclosure of statistical tests and has rejected claims 19-21 over the ‘621 patent in combination with the ‘182 patent on that basis.

The disclosure of statistical tests in the ‘182 patent (based on the Examiner’s interpretation of the ‘182 patent) does nothing to overcome the insufficiencies of the ‘621 patent in not disclosing a processor programmed to determine whether a sample is indeterminate for the presence of a nucleic acid. In other words, the ‘182 patent does not supply what the ‘621 patent lacks, *i.e.*, a disclosure of a processor programmed to determine

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whether a sample is indeterminate for the presence of a nucleic acid in a sample. Thus, the combination of the '621 patent and the '182 patent does not render obvious the invention of amended claims 19-21. Withdrawal of the rejection of claims 19-21 under 35 U.S.C. § 103(a) over the '621 patent in view of the '182 patent is respectfully requested.

CONCLUSION

The foregoing amendments and remarks are believed to fully respond to the Examiner's rejections. The amended claims are in condition for allowance. Applicant respectfully requests allowance of the claims, and passage of the application to issuance.

Respectfully submitted,



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